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DEVICES AND METHODS FOR THE REPAIR OF ARTERIES

Field of the Invention

The present invention relates to devices and methods for the repair of arteries, and in particular to devices and methods for retaining grafts on arteries, methods of delivering such devices to arteries, devices for supporting catheters within arteries and devices for dilating arteries.

Background of the Invention

For clinical applications, tubular grafts made of woven, moulded or extruded synthetic polymeric or elastomeric materials are commonly used to replace natural tissue within a living organism which either is diseased or has suffered trauma. Commonly known in the art, grafts are sutured in place during an open surgical procedure or are held in place by stents in a combination known as a stent-graft. Some stent-grafts use barbs to fix the implant into the body conduit but successful stent-grafts can be complex and expensive to manufacture and, because of their rigidity, their use can be restricted to only straightforward surgical cases.

Stent-grafts, whose use now has a several years of history, show a tendency to migrate two to three years after implantation. Such an event currently requires major open surgery to replace the graft.

Other types of flat graft or patches are used to cover tissue damage. These grafts are also sutured or stapled in position during open surgery, but nevertheless also have a tendency to migrate.

Summary of the Invention

In a first aspect of the present invention, there is provided a device for retaining a graft on an artery, comprising a first part for contacting the graft and a second part for contacting the artery when the device is pierced radially through the graft and the artery wall, the first and second parts being connected by a resilient member, wherein the resilient member biases the first and second parts towards each other into a retaining

configuration such that in use the artery and the graft are retained together between the first and second parts of the device, and wherein the first and second parts are moveable into an open configuration in which they are further apart than in the retaining configuration to enable the device to be conveyed along an artery.

By graft is meant any material used to repair or support damaged or weak conduits within a living organism, including arteries and veins. The graft may be formed from woven, moulded or extruded synthetic polymeric or elastomeric materials and may be tubular or flat (i.e. a patch).

The fixator here defined is arranged so that fully invasive surgery is not required and access to a site within a living organism is achieved by minimally invasive surgery which includes endovascular, percutaneous or translumenal approaches. The fixator can be used to attach a conventional vascular graft or other endolumenal vascular implant from within the artery.

The retaining system used to fix and secure grafts consists of two components: the fixation device and an introducer.

The introducer comprises a pair of catheters which lie one within the other. The fixator catheter is flexible but has sufficient stiffness to oppose the reaction force created when the fixator pierces the graft/artery. The fixator catheter has an angled head which directs the fixator through the wall of the graft. The fixator catheter lies within the sheathing catheter which is another flexible catheter with a stiff section at its tip. When the fixator catheter is withdrawn into the sheathing catheter, the angled head of the fixator catheter is straightened by the stiff tip of the sheathing catheter.

By catheter is meant any suitable conduit or tube for inserting into a living organism to deliver or remove the devices of the present invention. The catheters are constructed of suitable flexible materials, substantially round in section and of diameters that can pass

through natural body conduits or small incisions, to reach a site that may require a tubular graft or flat, patching material to effect a surgical repair to body parts.

In a second aspect of the invention, there is provided a device for supporting a catheter within an artery or arterial graft, the device having a locating member for locating the device with respect to the catheter and at least one support member for supporting the catheter on the inner wall of the artery or graft, wherein the support member and the locating member are connected by a resilient member which biases the support member towards the artery wall.

In a third aspect of the invention, there is provided a method for delivering a retaining/fixation device as defined above to a locus of a conduit (such as an artery), comprising the steps of moving said first and second part of the device into said open configuration, inserting the device into a catheter, positioning an end of the catheter at the locus, and moving the device down the catheter until the device emerges from said end of the catheter at the locus. The method may additionally comprise the step of employing a supporting device as defined above to support the catheter within the conduit.

By locus is meant the position in the conduit to which it is desired to deliver the fixation device. This may be a specific place on graft. The relevant end of the catheter may be positioned so that it touches the graft, or it may be positioned an appropriate distance from the graft (such as about 1.5mm) to enable the fixation device to exit from the catheter and pierce the graft and then the artery without first springing into the open configuration.

The supporting device locates the catheter securely on the axis of the tubular vessel into whose wall the fixation device is to be inserted. The supporting device provides a stable platform to provide adequate lateral force for the fixation device to pierce the wall of the

graft and then the natural tissue. The supporting device also fixes the angle at which the fixation device penetrates the wall of the graft.

Preferably, the supporting device preferably holds the tip of the fixator catheter firmly against the wall of the graft so that the fixation device is constrained and cannot deploy until after it has penetrated the wall of the graft.

The fixation device is constructed of a material that has sufficient elastic or shape memory recovery properties to be deformed into a substantially straight form and may be constrained in said form within a catheter. Upon ejection from the catheter, the fixation device is able to spring back to its manufactured shape to lock the graft to the natural tissue.

A preferred embodiment of the fixation device preferably consists of a plurality of wires lying parallel to each other and connected together in the centres of their long axes by welding or other mechanical fixation means such as binding with a wire or sheathing with a bush of metal or polymer. The binding or bushing means can usefully be made of a radio-opaque material such as tantalum or barium-loaded polymer.

In an alternative embodiment, the fixation device is constructed from a single piece of material which is shaped into a plurality of wires.

Two, three, four or more wires may be connected at their central portions; the free parts of the wires are arranged to curl tightly outwards to form a nearly-closed hook. The collection of hooks thus formed, when connected at the weld, resemble a double-ended marine anchor known as a 'grapnel' or grappling iron. Preferably, the weld joining the wires lies equi-distant from the ends of the wires. The symmetry of the design ensures that the fixation device will not rotate or tumble in its location and those embodiments with three or more wires are stable in all dimensions.

The fixation device can be constructed of round, square or triangular section wire. All these types of construction are preferably connected in their central area, as described. A four wire version, in plan, is cruciform, the three wire is tri-form and so on.

Each wire, which is preferably constructed of an equi-atomic nickel-titanium shape memory alloy has, by elastic recovery or by thermally induced shape recovery means, a geometry which forms into a shape which when introduced through puncturable materials, retains one puncturable material in relation to other puncturable material. To puncture said materials, each wire preferably has a leading edge sharpened, the trailing edges being flat or rounded, preferably concave.

Each wire preferably has a diameter of from 0.1mm to 0.7mm, and most preferably about 0.4mm. The length of each wire may be in a range from 4mm to 25mm, and preferably 15mm.

In a preferred embodiment, the distance between the end of the wires at one end of the fixation device is about 1mm in the open configuration and about 10mm in the retaining configuration.

The wires are preferably sharpened with an oblique point of elongate ellipsoid form so that when the wires are constrained in a catheter before delivery, the bundle of wires is sharpened to a single point.

In one embodiment, a plurality of fixation devices are constrained in line in a delivery catheter and are ejected by a flexible pusher wire that pushes on the last fixator in the line, which in turn pushes on the next and so on. The number of fixators ejected is appropriate to the anatomical site and the conduit strength and size. Another embodiment involves individual fixators which may be deployed one at a time by loading the delivery catheter with a single fixator, ejecting said fixator and re-loading the catheter.

In another embodiment of the fixator, an open ring of wire is constructed from a material exhibiting either thermal effect shape recovery or elastic shape recovery and can also be used for graft fixation. The ring may be of circular or elliptical form. The dimensions of the fully deployed ring fixator are arranged so that suitable forces are generated to ensure intimate contact between graft and natural tissue. This embodiment is the simplest to construct and is potentially capable of the greatest miniaturisation for delivery in small catheters.

The ring is deformed into a straight form by urging it into the bore of a substantially straight catheter. It is then pushed through the lumen of the catheter by a pusher wire or similar means and expelled from the proximal end of the catheter. The pusher wire or similar means is capable of exerting sufficient axial force on the fixator to cause it to travel through the lumen of said catheter and penetrate at least the said graft material and the living tissue behind it. Subsequent to penetration of the graft and living tissue the ring regains its round or elliptical shape, effecting fixation of graft and living tissue.

The embodiment just described can be extended to include a plurality of rings joined end to end to form a helix. The helix has a sharpened leading tip, such that when the helix is rotated, it screws itself around the wall of the graft material. Thus in the case of a tubular graft, the helix would follow the wall of the graft to form a broken annulus while each turn of the helix would puncture the graft material and the vessel wall in turn. The said rotation can be easily achieved when the helix is fabricated from thermal effect or super-elastic shape memory alloy. Upon exiting a delivery device which constrains the wire to be nominally straight, and upon heating in the case of thermal effect material, the wire will roll itself back into the helical form. When suitably approximated to the graft material, the rolling action will thread the helix into the material.

Accordingly, in a fourth aspect of the invention, there is provided a device for retaining a graft on an artery, comprising an elongate member formed of a resilient material which

biases said member into a helical configuration, at least one end of the member being sharpened to enable the member to pierce through the graft and the artery wall, wherein the member is moveable into an open configuration in which it can be conveyed along an artery.

In a fifth aspect of the invention there is provided a method for delivering a helical fixation device as defined above to a locus of a conduit, comprising the steps of moving said helical member into said open configuration, inserting the device into a catheter, positioning an end of the catheter at the locus, and moving the device down the catheter until the device emerges from said end of the catheter at the locus. The supporting device defined above is preferably employed to support the catheter within the conduit whilst the helical device is being delivered.

A specific application of the preferred fixator system is the fixation of a vascular graft in the human aorta for the repair of abdominal aortic aneurysms. The graft, typically a woven or knitted polyester, single or bifurcated tube, is attached to the fixator catheter by a simple fracturable, shearable or withdrawable connector, such as a thin suture material, the attachment being around the outside of the fixator catheter. This assembly is then placed in a sheathing catheter and introduced endovascularly to the aneurysmal site. The connector is caused to release the graft from its catheter by active mechanical means such as an integrated cutting edge or scissors. Electrical resistance heating of a small wire engaged with the catheter-to-graft attachment can be utilised to disconnect the attachment.

The leading end of the fixator catheter is then guided to the inner wall of the graft and a fixator is ejected. As the fixator is ejected it is urged through the graft and aorta, its shape changing from a nominally straight to multiple-arcuate, each arm facilitating graft fixation.

When the fixator is fully deployed the geometry is arranged so that a small compression force is developed, urging the outer surface of graft into intimate contact with the inner

surface of the aorta. When intimate contact between the aorta and graft is maintained around the circumference of the graft it will ensure that blood does not leak past the graft-aorta connection. The fixators also ensure that the graft cannot migrate and any physiological forces that attempt to expand the aorta radially will be constrained by said fixator arrangement.

To achieve a leak-free graft connection, several fixators are required, introduced from inside the lumen of a body conduit. For vascular graft applications an endovascular or translumenal approach is employed, the leading edge of the catheter making a quasi-perpendicular approach to the vessel wall.

To achieve the desired angle of said catheter, a centralising mechanism (the supporting device defined above) is deployed in order to establish the spatial relationship of the catheter to the vessel.

At least one strip or one wire, which is elastically deformable, is folded length-wise in half. When the wire or strip is held at the ends but is otherwise unconstrained, it will spring into a near circular or oval shape. The folded strip can be drawn into a catheter and this action will compress it to be an almost flat bi-layer. Upon partial expulsion from the catheter, with the ends of the strip or wire still retained in the catheter, the strip or wire will spring back to its near oval shape. When it expands to its near oval shape, the strip or wire expands symmetrically about the axis of the catheter.

If the strip or wire oval is deployed within a cylindrical vessel so that it is a snug fit between the walls of the vessel, the vessel, the strip or wire oval and the catheter may be aligned coaxially. The stiffness of the strip or wire loop is such that the catheter is held firmly in the centre of the cylindrical vessel. Equally, the elasticity of the strip or wire oval is such that the oval will fit a wide range of sizes of vessel.

A single piece of wire and preferably a single wide strip is particularly useful for use in small arteries. When deployed, the strip or wire oval does not significantly reduce the flow of blood through an artery.

Preferably, a second and optionally further strip or wire loops are used, orientated so that, in plan view, the loops are coaxial but uniformly radially distributed around the axis.

The strip or wire preferably has a diameter from 0.3mm to 5mm, and more preferably about 1.5mm. When in the supporting configuration, the looped embodiment of the supporting device may be from 4mm to 50mm when measured transversely across from one support member to another (i.e. the diameter of the loops).

The strips or wires can be pulled inside the catheter by means of a pushing or pulling wire. Equally, the retracted strips may be expelled from the constraining catheter by the pulling or pushing wire.

When retracted, the catheter enables the centralising mechanism to be transported within a narrow passage without causing interference or trauma to the passage.

Also contained within the catheter is a tube which may be made from an elastically deformable material such as PTFE or nylon. Preferably the tube is formed from super-elastic shape memory alloy such as nickel-titanium. The dimensions of this tube are such that it will allow straightened fixators to pass through its bore without interference. A typical range for the diameter of the tube is from 0.3mm to 5mm. Preferably, the inner diameter is about 1.5mm and the outer diameter is about 1.7mm. Said tube is configured such that it is extendible or retractable within the catheter. Extension and retraction is manually controlled.

The proximal end of said elastic tube is heat-treated to produce a radius that subtends an angle to the conduit wall. Preferably, the angle is between 10° and 90° and more preferably 45°, but the device will still function even if the conduit wall curves sharply away from the catheter, since glancing angles can be accommodated by the device.

The present invention also relates to a medical dilation device which may be used to dilate an occluded conduit, expand a stent or facilitate circumferential conformity when fitting a tubular graft inside a vessel residing in a living organism.

Percutaneous Transluminal Coronary Angioplasty (PTCA) is a well known technique, commonly used in clinical maintenance or repair of certain fluid carrying vessels within a living organism. The technique requires the hydraulic expansion of a compliant balloon which is sited in a vessel that requires radial expansion. PTCA, although usually applied to the dilation of coronary arteries, is a technique that has been applied to other conduits requiring dilation.

A stent may be used to continually support a dilated vessel or graft, ensuring luminal patency of said vessel or graft. Stents are generally metal constructions with perforated walls that may be radially expanded when positioned in the lumen of an occluded vessel by placing a balloon inside a stent and inflating the balloon. This increases the diameter of the stent which plastically deforms due to balloon inflation.

In addition, the placement of grafts and graft-stents combinations within a natural vessel, can benefit from an internally expanding balloon to urge the outer surface of the graft or graft-stent in intimate contact with the inner wall of the said vessel.

PCTA balloons may be inflated with hydraulic media using pressures up to 20 Atmosphere. However, it is not always possible to expand the balloon with sufficient pressure to effect suitable radial expansion. For example, fibrous lesions inside a vein may be formed from a tough and tenacious fibrous material which may resist the dilatory

efforts of the balloon. There is also a danger of rupture, leakage or bursting of the balloon when used at relatively high pressures.

As dilation balloons become fully dilated in arterial vessels, blood flow in the artery is prevented or severely limited. Ischemic problems may arise if blood flow is curtailed for an extended period. This is particularly relevant for vessels associated directly with the cardiovascular system such as the coronary arteries.

Accordingly, in a sixth aspect of the invention, there is provided a device for dilating an artery when delivered translumenally to a locus of an artery by means of a catheter, having a locating member for locating the device with respect to the catheter and a plurality of dilating members, each of which is connected to the locating member by a resilient member which biases the dilating member towards and into contact with the inner artery wall, wherein in use the resilient members cause the dilating members to apply outward pressure to the inner artery wall in order to dilate the artery.

The device preferably comprises at least one resilient wire disposed in a loop with the ends of the wire being locatable in an end of a catheter, wherein in use the sides of the loop contact the inner artery wall and apply outward pressure thereto in order to dilate the artery.

The inventive device employs direct mechanical connections rather than fluid pressure to expand a vessel, stent or graft or graft stent. It has the advantage of not fully occluding the blood vessel.

Summary of the Drawings

Preferred embodiments of the present invention will now be described by way of example, with reference to the accompanying drawings, in which:

Fig. 1. shows a plan view of a wire-form fixator;

Fig. 2. shows plan views of alternative wire-form fixators;

Fig. 3. shows schematically in cross-section the use of fixators in accordance with the invention;

Fig. 4. shows an alternative fixator;

Fig. 5. shows in cross section the delivery of fixators in accordance with the invention;

Fig. 6. shows in cross section the delivery of an alternative form of fixators in accordance with the invention;

Fig 7. is a perspective view, in partial cross-section, of various fixators in accordance with the invention;

Fig 8. and Fig. 9 illustrate a method of securing a graft to an artery in accordance with the invention;

Fig. 10 illustrates a stabilising device in accordance with the invention in its various configurations;

Fig. 11 illustrates apparatus for deploying a stabiliser device and for delivering fixators in accordance with the invention;

Figs. 12 to 16 illustrate various dilators in accordance with the invention and apparatus for delivering the dilators to an artery.

Detailed Description of Preferred Embodiment of the Invention

Referring to the drawings, Fig. 1. illustrates a plan view of a wire-form fixator [2], connected by welding in the central area. The end termination of the fixator are sharpened and shown in the unconstrained (retaining) configuration.

Fig. 2. illustrates methods of connecting fixator wire-forms [3], preferably by welding [6] but alternatively binding [5], a crimping bush [4]. The cross-section is shown using four wires [7], three wires [8] and two wires [9]. All are in the constrained (open) configuration.

Fig. 3. shows schematically in cross-section, fixators [12] engaging a graft [10] with aorta [11].

Fig. 4 illustrates a ring form fixator in the retaining configuration [13] and in the open configuration [14].

Fig. 5. is a view showing ejection of fixators [18] from catheter [17] and deformed and constrained fixators [16]. The ejecting wire [15] exits from the distal end of the catheter.

Fig. 6. shows an alternative ring fixator [19] being ejected from the tip of the catheter [22]. Means for ejecting ring fixator is by pusher wire [23]. A fully formed ring fixator is shown [13].

Fig 7. Shows embodiments of fixator arrangements in the form of two wire-form [26], three wire-forms [25] and four wire-forms [24].

Fig 8. Shows the embodiment whereby fixators approach an artery [33] at 90° to the long axis. An elastically deformable tube [32] forms a 90° arc when extended from its constraining catheter [34], by means of a pushing or pulling wire [35].

Fig. 9. Shows a means to retract the fixator delivery tube by pulling the pushing\pulling wire [35], causing the tube to be drawn inside the catheter.

A graft fixator system will now be described in detail with particular reference to Figures 10 and 11.

A graft fixator system consists of a delivery system and one or a series of fixators. The delivery system is comprised of the following elements: A hand held device to control and determine fixators ejection, to deploy a stabilising device and the fixator delivery tube. The hand held controller of similar external form to a hand-held gun, consists of a trigger used to eject fixators a sliding and rotatable barrel used to deploy the fixator delivery tube\stabiliser assembly and to rotate the delivery tube assembly.

The hand-held device Fig 11. has three functions. To eject fixators, to deploy the fixator delivery tube and to deploy the stabiliser system. When squeezed, the trigger (37) ejects fixators. The trigger mechanism is connected directly to a wire (40) which pushes against the fixators. To ensure adequate penetration of the fixators, operation of the trigger impacts the fixator by a spring-assisted release when the trigger is pulled. This mechanism is identical to the mechanical configurations found in an automatic hand pistols which also require an impacting force against a bullet cartridge. The sliding and rotatable barrel (41) deploys both stabiliser and fixators. The barrel is mechanically connected to the stabiliser deployment tube (39) and fixator eject wire (40). Linear movement of the barrel produces an equal movement of the stabiliser, deployment mechanism and fixator eject wire (39, 40).

The stabiliser (Fig.10) consists of two elastically deformable thin strips of metal (47) which, when unconstrained form a nominally circular shape (46). The two strips are riveted together (45) at the leading edge and are riveted onto a short metal tube (49) which has been arranged to retract within a catheter sheath (48).

The fixator delivery tube (Figs. 8 and 9) is contained within a constraining sheath until it is push-out by a pusher-wire, operated by linear actuation of the gun-barrel. Equally, it can be drawn back into its sheath by pulling the wire. The fixator delivery tube is made from a super-elastic nickel-titanium alloy that has a pre-formed radius at its tip (32). As it is pushed out of its constraining catheter, by elastic shape recovery, the radius forms

which is arranged to abut against a natural tissue wall or a graft fitted coaxially within the natural tissue wall. The stabiliser and fixator tube deployment are operated by the same push-pull wire.

To use the graft fixator, access to the living organism has to be made at a suitable site, for example, in a human being, the femoral artery, close to the groin, would be used to subtend a pathway to the arterial system. The catheter sheath containing the graft fixator delivery system, enters the vascular pathway and may be guided to an appropriate site by means of a guide-wire through the centre or on the side of the fixator delivery assembly. The delivery assembly is progressed through the organism until it reaches the required position. This may be determined by angiographic techniques or ultra-sound or other suitable medical visualisation devices.

The gun-like controller barrel is then pushed forward, this deploys the cruciform stabiliser and fixator tube. The slidable barrel has two control positions. One extends the delivery tube, the other extends and deploys the stabilising cruciform device. The two positions are indicated by a graduated linear scale positioned on the static part of the barrel assembly.

Due to the radiused tip of the fixator delivery tube, as it is deployed from its constraining sheath a radius forms (due to elastic recovery) and abuts against the selected vessel wall. If the correct positioning of the fixator delivery assembly has been determined, the gun-handle trigger is depressed which ejects a fixator.

The graft fixator system is capable of ejecting one or several fixators which may be disposed around the circumference of an implanted graft to ensure that leak paths between the natural conduit and graft, are eliminated. A plurality of fixators may be used by the following means:

After one fixator is ejected, the linear\rotatable barrel is slid-back to a point indicated a graduated scale. It is then rotated and slid forward. This draws the fixator delivery tube into its sheath, constraining it as a straight-tube, rotation of the barrel also rotates the delivery tube.

Fixator deployment sequence is the same as described previously: The rotated barrel is pushed forward, the delivery tube now is extrudes from its sheath in a new position on the inner circumference of the graft. A second fixator is now deployed which is radially offset by approximately 45° relative to the first. Subsequent fixators may be positioned clockwise or anti-clockwise as long as the rotational direction remains the same for each fixator.

When sufficient fixators have been deployed, the sliding barrel is fully retracted, sheathing the delivery tube and stabilser, the entire catheter may now be withdrawn from the organism.

Preferred embodiments of dilators in accordance with the invention will be described with reference to Figures 12 to 16.

Fig. 12 is a schematic representation of the wire-form dilator in plan (104) and a side view (105), showing the delivery catheter (106).

Fig. 13 illustrates methods of forming the distal end of a dilator (110-112) and shows schematically, a single wire-form dilator element (107-109) and a wire-form deployment and envelope expansion mechanism in the from of a pulling wire (119) and a pushing\pulling tube (120).

Fig 14 illustrates schematically the wire-form dilator being drawn into its sheath or catheter (113 - 116).

Fig 15 illustrates schematically the use of the pulling wire (119) and pushing\pulling tube (120) to increase the wire-form envelope diameter (121) .

The construction of the dilation device consists of a plurality of wires (105), or thin strips, preferably made from a super elastic alloy, pre-formed into a substantially ellipsoidal (107) shape with one end open (109) and extended (108). The other end of the dilator terminates with the plurality of wire joined together by means of welding (110), crimping with a bush (111) or binding with a suitable wire or cord (112). The wires are configured with suitable elastic recovery properties so that they may be deformed and constrained to a minimised volume for introduction and transportation within a living organism. This is achieved by pulling the wire-form inside a sheath (113 - 116). If the constraining influence is removed, the wires resume a shape by elastic recovery. The restraining mechanism is a sheath of suitable dimensions so that the wires may be drawn into their retaining and constraining sheath (106), by drawing them into the sheath by means of small tube (120), preferably formed from a super elastic alloy as described. The tube is connected to each of the terminal ends of the wire-form balloon by welding, riveting or hard soldering.

Another elastically deformable wire (119) is positioned inside the tube (120) and connected to the leading edge of the wire-form balloon by welding, binding or by a crimped bush. The wire (119) can slide freely through the tube (120).

A nominal outer envelope diameter of the wire-form assembly is established by virtue of the elastic shape recovery of each wire-form element.

The unconstrained, elastic recovery of the wire-form may have sufficient hoop energy to effectively expand a stent or graft or natural vessel but, by utilising a wire to pull the end tip of the wire-form balloon and at the same time preventing the trailing-end of the device from moving, the wire-form can adopt an increase in its diametrical envelope. Equally, the wire-form envelope may be reduced by preventing the pulling wire (119)

from moving while pulling the tube (120), to a pre-determined position. This enables one wire-form device to be used for dilation purposes within vessels of different diameters. The range of dilation diameters required would be from 4.0mm to 30.0mm.

The geometry of the wire-form balloon is preferably ellipsoidal in section although the shape may be configured for particular medical situations. For example, coronary occlusive disease which requires dilation of the vessels to re-instate luminal patency, should have a nominal diameter in an adult and when in good condition of approximately 4.0mm. However, the length of said lesions are typically up to 20mm. A wire-form balloon for this task will be long but relatively small in diameter. Tumorous growth in the oesophagous which may need dilation and stent support as a palliative measure, requires a wire-form with a different diameter-to-length relationship, for example a diameter of from 20 to 30mm and a length of from 50 to 60 mm.

A preferred embodiment of a wire-form balloon consists of a flexible tube or catheter (106), containing wires having a predetermined shape when unconstrained (107). Said wires may be drawn into said flexible tube and constrained within the volume of the sheath. The geometry, in plan of the wire form consists of a series of arms radiating outwards (104), from the centre of the wire-form device. The number of said arms radiating outwards can be arranged from a minimum of two to a maximum of twenty.

The wire-forms, preferably constructed from super-elastic shape memory alloy, such as nickel-titanium, or nickel-titanium-copper or nickel-titanium-copper-chromium, may be drawn within the lumen of said sheath by means of a pulling tube (120). Elastic shape recovery of the wire-forms may be sufficient to effect suitable vessel dilation; additional expansion may be facilitated by pulling the proximal end of the wire-form balloon, normal to its long axis while constraining the distal ends of the wire-forms. This expands the diameter of the wire-form (121), reducing its length.

A specific embodiment of the dilator will now be described with reference to Figure 16.

A dilator comprises a plastic tube (120) made from PTFE with an outside diameter of 1.65mm and an internal diameter of 1mm. The catheter is between 1m and 1.5m long. Through the catheter runs a 316 stainless steel or Nitinol actuator wire (219) of 0.5mm in diameter. At one end of the wire is attached a proprietary handle, commonly known as a 'torquer'. This end is intended to remain in the hands of the medical practitioner.

At the other end of the catheter a set of thirteen wires (205) made of superelastic Nitinol, 0.3mm in diameter by 70mm long are arranged circumferentially around the catheter and parallel to the axis of the catheter. The wires are retained on the end of the catheter by means of a stainless steel sleeve (221) which is 5mm in length and has a wall thickness of 0.2mm. The sleeve is crimped around the 13 Nitinol wires such that the wires project 60mm beyond the end of the catheter. In order to provide a smooth outer surface to the region of the crimp, an elastic or heat-shrinking sleeve (222) of 15 mm length is applied over the sleeve.

The actuator wire emerges the end of the catheter and lies at the centre of the 13 Nitinol wires so that they are uniformly radially distributed about it. The tip of the actuator wire is crimped or glued into a stainless steel bush (223) of 1.65mm diameter and 8.5mm in length. The actuator wire does not pass through the bush. The tip of the bush is rounded to provide a smooth, atraumatic tip for the device.

The 13 Nitinol wires are radially distributed around the bush and are attached to it by means of a second sleeve which is identical to that retaining the wires to the end of the catheter. Similarly, a heat shrink sleeve of 15mm length is applied over the sleeve and bush to render the surface of the region smooth.

The Nitinol wires may be pre-formed to have a slight bend in the centre of their bodies which, during assembly, is arranged to be directed away from the main axis of the whole device. In this embodiment, the wires are mounted firmly in a bushes at either end of

their extent. The bushes are drilled or have otherwise formed in them holes which are uniformly radially arranged to retain the Nitinol wires in their preferred orientation. The wires are securely fastened in the radially arranged holes by means of gluing crimping welding or other permanent attachment means. Moreover, a bush at one end of the wires (the first bush) is firmly attached to the tip of the catheter by gluing, crimping, force-fitting or sleeving so that it cannot rotate. The second bush is firmly attached to the actuator so that similarly, it cannot rotate. The actuator wire is preferably not circular so that an aperture with a mating internal form can be used in the catheter or, conveniently, the centre of the first bush, so as to prevent rotation of the actuator wire about the axis. The actuator wire can conveniently have a cross section which is oval or rectangular, although other shapes are possible.

The advantage of this embodiment is that the 13 Nitinol wires are more likely to remain uniformly distributed around their central core. This is of particular significance when the actuator wire has been pulled and the 13 Nitinol wires are caused to bulge out laterally from the central axis of the device.

It is desirable that all embodiments of the dilator have sufficient space through the lumen of the catheter, between the Nitinol wires and through the bush at the tip of the device to permit the device to be threaded over a guide wire typically of 0.035" diameter (0.88mm). This can be effected by introducing an additional lumen to the catheter, by employing a hollow actuator wire or by selecting actuator and guide wire size that will fit appropriately within the catheter.

For the avoidance of doubt, "artery" as used herein means any vessel or conduit in a living organism, including but not limited to arteries, veins and capillaries.